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L37: Entry 5 of 93 File: PGPB Mar 25, 2004

DOCUMENT-IDENTIFIER: US 20040058446 A1
TITLE: Compositions and methods for drug delivery using pH sensitive molecules

Summary of Invention Paragraph:
[0282] Polymers with labile bonds may have the following generalized structures: A-B-A where A is a monomer and B is a pH-labile linkage, A-B--C where A is a monomer and B is a pH-labile linkage and C is an interaction modifier. The modifying group may confer the polymer with a varieties of new characteristics such as a change in charge (e.g. cationic, anionic), cell targeting capabilities (e.g. nuclear localization signals), hydrophilicity (e.g. polyethyleneglycol, saccharides, and polysaccharides)i and hydrophobicity (e.g. lipids and detergents). The labile group may be added to the polymer during polymer synthesis or the labile group may be added to the polymer after polymerization has occurred.

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L38: Entry 15 of 36 File: PGPB Aug 22, 2002

DOCUMENT-IDENTIFIER: US 20020115216 A1
TITLE: Composition for delivery of compounds to cells

Summary of Invention Paragraph:
[0003] In the early 1970s the first human genes were transferred into mammalian cells in the form of hybridomas. Since that time, scientists have been coercing nucleic acids into vertebrate cells. The introduction of nucleic acids into cells permits correcting a genetic deficiency or abnormality, for instance mutations, aberrant expression, and the like. The introduction of nucleic acids into cells can also be used to cause expression of a therapeutic protein in the affected cell or organ. This genetic information may be introduced either into a cell extracted from an organ, the modified cell then being reintroduced into the body, or directly in vivo into the appropriate tissue. Many advances have been made in the delivery of nucleic acids to cells, including the use of viral vectors and transfection techniques using cationic lipids and cations polymers to complex nucleic acids. However, there remains a need for methods to deliver nucleic acids to cells.

Summary of Invention Paragraph:
[0008] In another aspect, the invention provides a method for making a cationic polymer:targeting group conjugate. One embodiment of the method encompasses converting a lactose to an aldonic acid, then combining the aldonic acid, a polyethyleneimine and 1-ethyl-3-(dimethylaminopropyl)-car- bodiimide under conditions suitable for coupling the aldonic acid to primary amines of the polyethyleneimine to yield the cationic polymer:targeting group conjugate. Another embodiment of the method encompasses combining a lactose, a polyethyleneimine, and 1-ethyl-3-(dimethylaminopropyl)-carbodiimide under conditions suitable for coupling the lactose to primary amines of the polyethyleneimine to yield the cationic polymer:targeting group conjugate.

CLAIMS:

13. A method for making a cationic polymer:targeting group conjugate comprising: converting a lactose to an aldonic acid; and combining the aldonic acid, a polyethyleneimine and 1-ethyl-3-(dimethylaminopropyl)-car- bodiimide under conditions suitable for coupling the aldonic acid to primary amines of the polyethyleneimine to yield the cationic polymer:targeting group conjugate.

14. A method for making a cationic polymer:targeting group conjugate comprising combining a lactose, a polyethyleneimine, and 1-ethyl-3-(dimethylaminopropyl)-carbodiimide under conditions suitable for coupling the lactose to primary amines of the polyethyleneimine to yield the cationic polymer:targeting group conjugate.

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L38: Entry 32 of 36 File: USPT Jul 31, 2001

DOCUMENT-IDENTIFIER: US 6268053 B1
TITLE: Macromolecular microparticles and methods of production and use

Brief Summary Text (30):
It is a further object of the present invention to provide microparticles for use in medical and diagnostic applications, such as drug delivery, vaccination, gene therapy and histopathological or in vivo tissue or tumor imaging.

Detailed Description Text (29):
Molecules, distinct from the macromolecules of which the microparticles are composed, may be attached to the outer surface of the microparticles by methods known to those skilled in the art to "coat" or "decorate" the microparticles. The ability to attach molecules to the outer surface of the microparticle is due to the high concentration of macromolecule in the microparticle. These molecules are attached for purposes such as to facilitate targeting, enhance receptor mediation, and provide escape from endocytosis or destruction. For example, biomolecules such as phospholipids may be attached to the surface of the microparticle to prevent endocytosis by endosomes; receptors, antibodies or hormones may be attached to the surface to promote or facilitate targeting of the microparticle to the desired organ, tissue or cells of the body; and polysaccharides, such as glucans, may be attached to the outer surface of the microparticle to enhance or to avoid uptake by macrophages.

Detailed Description Text (74):
The microparticles are also useful as vehicles for gene therapy or the production of "genetic vaccines" when composed of nucleic acids, such as DNA or RNA, that are either incorporated into the DNA of the patient or are transfected into a target cell to produce a desired protein. For example, polynucleotides encoding core proteins of viruses such as influenza or human immunodeficiency virus HIV can be delivered as microparticles for expression of an antigenic protein. This is advantageous in that new vaccines need not be developed as often because viral core proteins mutate to a much lesser extent than the cell surface antigens currently used in vaccines. The nucleic acid microparticles are delivered to mammalian cells in much the same way as naked DNA is delivered. The desired nucleic acid sequence is inserted into a vector, such as plasmid DNA, with a promoter, such as the SV40 promoter or the cytomegalovirus promoter, and optionally may include a reporter gene, such as beta-galactosidase. The nucleic acid is preferably combined with a carrier protein and/or a cation, such as polylysine, to facilitate particle formation as described above. The microparticles are then administered directly to the patient or are transfected into mammalian cells that are then administered to the patient requiring therapy or prophylaxis. The nucleic acid microparticles may include a substance such as chloroquine, which allows nucleic acids to escape from cytoplasmic compartments into the cytoplasm so that it can be more easily transcribed and translated by the cells. Additionally, the microparticles may be coated with a substance that increases the efficiency of translation or may be coated with a substance to provide cell-specific targeting of the microparticles.

L42: Entry 82 of 104 File: USPT May 1, 2001

DOCUMENT-IDENTIFIER: US 6224903 B1
** See image for Certificate of Correction **
TITLE: Polymer-lipid conjugate for fusion of target membranes

Detailed Description Text (60):
In one embodiment, release of the hydrophilic segment from the polymer-lipid conjugate is mediated by an enzyme that is present at the desired target site. In this embodiment, the releasable linkage between the hydrophobic and hydrophilic segments contains an amino acid sequence that is specifically or preferentially cleaved by an extracellular enzyme or by an enzyme attached to a cell surface at the target site. Such enzyme-cleavable amino acid sequences can be determined by screening phage display libraries (Buchholz, C., et al., Nat. Biotechnol, 16 (10):951-954 (1998)). An exemplary amino acid signal sequence is PLGLWA, referred to herein as SEQ ID NO. 12. This sequence is cleavable by matrix metalloproteinases (MMPs), which are present in the extracellular fluid of tumor regions (Peng, K., et al., Hum. Gene Therapy, 8(6):729-738 (1997); Ioachim, E. E, et al., Anticancer Res., 18(3A):1665-1670 (1998)).

L47: Entry 43 of 56 File: USPT Apr 6, 1999

DOCUMENT-IDENTIFIER: US 5891475 A
TITLE: Particulate vector and pharmaceutical composition containing it

Brief Summary Text (16):
One object of the present invention is therefore to provide an efficient vector having a simpler structure. Surprisingly, it was found that particles comprising only a hydrophilic core, preferably consisting of a matrix of naturally or chemically cross-linked polysaccharides or oligosaccharides, and of an external lipid layer, make it possible to bind active ingredients having a biological activity and to considerably increase the efficacy thereof.

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L17: Entry 5 of 56 File: PGPB Dec 11, 2003

DOCUMENT-IDENTIFIER: US 20030228694 A1
TITLE: Transfection method and uses related thereto

Summary of Invention Paragraph:
[0011] A second embodiment of the method is referred to as a "lipid-DNA" embodiment. In this embodiment, a DNA-containing mixture (referred to herein as a lipid-DNA mixture) which comprises DNA (e.g., DNA in an expression vector); a carrier protein (e.g., gelatin); a sugar, such as sucrose; a buffer that facilitates DNA condensation and an appropriate lipid-based transfection reagent is spotted onto a surface, such as a slide, thus producing a surface bearing the lipid-DNA mixture in defined locations. The resulting product is allowed to dry sufficiently that the spotted lipid-DNA mixture is affixed to the slide and the spots remain in the locations to which they have become affixed, under the conditions used for subsequent steps in the method. For example, a lipid-DNA mixture is spotted onto a slide, such as a glass slide coated with .SIGMA.poly-L-lysine (e.g., Sigma, Inc.), for example, by hand or using a microarrayer. The DNA spots can be affixed to the slide as described above for the gelatin-DNA method.

Detail Description Paragraph:
[0187] Selectivity tests could also be performed on the metabolites of a drug candidate. For instance, a radiolabeled drug could be reacted with the appropriate biotransformation agent, such as a liver extract, tissue culture system, or living organism such as a rodent or dog. The radiolabeled metabolites could then be extracted and purified and tested for binding with the array. Metabolites with binding activity could then be characterized further by standard methods. Two embodiments of the present method are described in detail herein: a DNA-gelatin method, in which a mixture comprising DNA (e.g., DNA in an expression vector, such as, a plasmid-based or viral-based vector) and a carrier protein (e.g., gelatin) is used and a lipid vector-DNA method, in which a mixture comprising DNA, such as DNA in an expression vector (e.g., a plasmid); a carrier protein (e.g., gelatin); a sugar (e.g., sucrose); DNA condensation buffer; and an appropriate lipid-containing transfection reagent is used. Any suitable gelatin which is non-toxic, hydrated, which can immobilize the nucleic acid mixture onto a surface and which also allows the nucleic acid immobilized on the surface to be introduced over time into cells plated on the surface can be used. For example, the gelatin can be a crude protein gelatin or a more pure protein based gelatin such as fibronectin. In addition, a hydrogel, a sugar based gelatin (polyethylene glycol) or a synthetic or chemical based gelatin such as acrylamide can be used.

Detail Description Paragraph:
[0189] In the second embodiment, one example of which is described in Example 2, a mixture comprising DNA in an expression vector; a carrier protein (e.g., gelatin); a sugar (e.g., sucrose); DNA condensation buffer; and a lipid-based transfection reagent is spotted onto a surface, such as a slide, in discrete, defined locations and allowed to dry. Actively growing cells are plated on top of the DNA-containing locations and the resulting surface is maintained under conditions (e.g., temperature and time) which result in entry of DNA in the DNA spots into the growing cells (reverse transfection). Expression of DNA in cells is detected using known methods, as described above.

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L32: Entry 43 of 70 File: USPT Jan 28, 2003

DOCUMENT-IDENTIFIER: US 6511677 B1
TITLE: Polymerizable fatty acids, phospholipids and polymerized liposomes therefrom

Brief Summary Text (77):
The polymerized liposomes of the present invention may be utilized for the delivery of a wide variety of compounds, including vaccines, antigens, allergens and other therapeutic agents or diagnostics. They have particular utility in the oral and/or mucosal delivery of vaccines and antigen release devices. For example, the polymerized liposomes of the present invention may be designed to carry a wide variety of antigens including, but not limited to, diphtheria toxoid, influenza hemeagglutinin, ospA antigen from Lyme disease bacterium, and HTLV envelope protein antigen. Antigens to poliovirus, rhinovirus, rabies, vaccinia, Epstein-Barr virus, hepatitis, HTLV, herpes virus and human immunodeficiency virus are just examples of the many types of antigens which may be encapsulated into the liposomes of the present invention. They may also be utilized for the oral delivery of a wide variety of therapeutics, including but not limited to, chemotherapy agents, antibiotics, insulin, cytokines, interferon, hormones, calcitonin, hormones, fertility drugs, antiviral agents (ddI, AZT, ddC, acyclovir and the like), antibacterial agents, antifungal agents, DNA and RNA nucleotides.

Brief Summary Text (92):
The polymerized liposomes of the present invention can be used for the oral and/or mucosal delivery of a wide variety of therapeutics, including but not limited to, antineoplastic agents, antibiotics, antifungals, antimicrobials, vaccines, insulin, cytokines, interferon, hormones, calcitonin, fertility drugs, antiviral agents (ddi, AZT, ddc, acyclovir and the like), antibacterial agents, DNA and RNA nucleotides, i.e., useful for gene therapy.

Brief Summary Text (117):
Use of purified antigens as vaccine preparations can be carried out by standard methods. For example, the purified protein(s) should be adjusted to an appropriate concentration, formulated with any suitable vaccine adjuvant and encapsulated within the polymerized liposome. Suitable adjuvants may include, but are not limited to: mineral gels, e.g., aluminum hydroxide; surface active substances such as lysolecithin or pluronic polyols; polyanions; peptides; oil emulsions; alum, and MDP. The immunogen may also be incorporated into liposomes, or conjugated to polysaccharides and/or other polymers for use in a vaccine formulation. In instances where the recombinant antigen is a hapten, i.e., a molecule that is antigenic in that it can react selectively with cognate antibodies, but not immunogenic in that it cannot elicit an immune response, the hapten may be covalently bound to a carrier or immunogenic molecule; for instance, a large protein such as serum albumin will confer immunogenicity to the hapten coupled to it. The hapten-carrier may be formulated for use as a vaccine.